13:12:40

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

EXACT SCIENCES CORPORATION,)
)
Plaintiff,)
) C.A. No. 23-1319(MN)
v.)
)
GENEOSCOPY, INC.,)
)
Defendant.)

Monday, May 20, 2024
2:00 p.m.
Motion Hearing

844 King Street
Wilmington, Delaware

BEFORE: THE HONORABLE MARYELLEN NOREIKA
United States District Court Judge

APPEARANCES:

MORRIS NICHOLS ARSHT & TUNNELL LLP
BY: JACK B. BLUMENFELD, ESQ.

-and-

QUINN EMANUEL URQUHART & SULLIVAN LLP
BY: ANDREW BRAMHALL, ESQ.
BY: BRIAN P. BIDDINGER, ESQ.
BY: JIHONG LOU, ESQ.
BY: GAVIN FRISCH, ESQ.

Counsel for the Plaintiff

APPEARANCES CONTINUED:

ASHBY & GEDDES
BY: STEVEN J. BALICK, ESQ.

-and-

FOLEY HOAG LLP
BY: SARAH S. BURG, ESQ.
BY: DONALD R. WARE, ESQ.

Counsel for the Defendant

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13:48:10 THE COURT: All right. Good afternoon. Please be seated.

14:07:22 All right. Let's start with some introductions.

14:07:25 Mr. Blumenfeld.

14:07:28 MR. BLUMENFELD: Thank you, Your Honor. Jack Blumenfeld from Morris Nichols for the plaintiff. And at counsel table with me are Andrew Bramhall and Gavin Frisch from Quinn Emanuel. Behind them are Brian Biddinger and Jihong Lou also from Quinn Emanuel. There are also two client representatives, Alexandra Gorman and Carly Conway.

14:07:52 THE COURT: Thank you.

14:07:53 MR. BLUMENFELD: Sorry, Your Honor, one little

14:07:54 point of information. I don't know if it hit your attention
14:07:57 yet, but we filed a lawsuit last week on a continuation
14:08:01 patent. It's Civil Action 24-583, which we assume will be
14:08:07 assigned to you the day after tomorrow. I just wanted to
14:08:11 let you know.
14:08:12 Thank you.
14:08:13 THE COURT: Mr. Balick.
14:08:17 MR. BALICK: Hello, Your Honor.
14:08:18 THE COURT: Good afternoon.
14:08:19 MR. BALICK: Steven Balick from Ashby & Geddes
14:08:22 on behalf of the defendant, Geneoscopy with co-counsel from
14:08:26 Foley Hoag, Donald Ware and Sarah Burg.
14:08:29 THE COURT: All right. Good afternoon.
14:08:32 All right. So let me ask defendant first, what
14:08:34 is it that you plan to do with respect to commercial
14:08:39 distribution of ColoSense now that you have received FDA
14:08:42 approval?
14:08:44 MR. WARE: Your Honor, again, this is Donald
14:08:52 Ware. The intention is to await reimbursement decision by
14:08:59 CMS, by Medicare, before launching the product.
14:09:03 THE COURT: What's the status of that?
14:09:06 MR. WARE: I think it's just being initiated
14:09:09 perhaps this week. And I can't give you a prediction of
14:09:15 exactly how long that takes. I have seen some estimates of
14:09:20 nine to twelve months coming from Exact, and you just wait.

14:09:26 But the intention is not to launch the product until
14:09:31 Medicare confirms a reimbursement coverage and payers which
14:09:35 is then usually followed by payers, insurance companies
14:09:40 deciding to reimburse.
14:09:41 We're quite a ways from launch. The one
14:09:44 statement that has been made publicly by Geneoscopy is that
14:09:47 they are expecting launch late this year or early in 2025.
14:09:51 THE COURT: All right. Thank you.
14:09:54 All right. And for the plaintiff, regarding
14:10:00 Count One, which is infringement, you say defendant has
14:10:08 already infringed the '781 patent by commercially marketing,
14:10:12 using, offering for sale, or selling ColoSense as a
14:10:18 commercial laboratory developed test in or around July 23rd
14:10:24 through an online website and order form. And then you say,
14:10:29 it will continue to infringe by commercially making, using,
14:10:34 offering to sell, or selling the ColoSense upon imminent FDA
14:10:39 approval. All of the claims of the '781 patent are method
14:10:43 claims, so you're not really arguing as you said that you
14:10:48 think they've infringed by offering for sale or selling.
14:10:52 Right?
14:10:53 MR. BRAMHALL: Your Honor, this is Andrew
14:10:56 Bramhall from Quinn Emanuel for Exact Sciences. Your Honor,
14:10:59 that's mostly a preservation point on our end.
14:11:03 THE COURT: I'm asking because I'm trying to
14:11:05 figure out -- I understand the declaratory judgment aspect

14:11:08 and we'll get to that. I'm trying to figure out, Count
14:11:12 One -- and Count One, where is it that you say that they
14:11:15 have -- you have a well-pleaded complaint that they have
14:11:20 used it, that doesn't fall within the Safe Harbor?
14:11:25 MR. BRAMHALL: So, Your Honor, with respect to
14:11:28 LDT, laboratory developed tests, those are separate and
14:11:33 apart from the FDA approval process, so our contention at
14:11:36 least is with respect to any activities relating to the LDT
14:11:41 test.
14:11:41 THE COURT: Give me a paragraph I'm supposed to
14:11:45 be looking at.
14:11:46 MR. BRAMHALL: Sure, Your Honor. For example,
14:11:47 there is a number of them. 69 is one paragraph. This is in
14:11:52 the First Amended Complaint, if that's where you're looking.
14:11:56 THE COURT: All right. Let me read it. Again,
14:12:00 this offered for sale, sold, marketed, that's not an act of
14:12:09 infringement, so I don't know why you're saying that that's
14:12:11 preserving something. But it seems wrong to me and I keep
14:12:15 getting stuck on that.
14:12:17 So where is it -- I mean, what you say here is
14:12:20 the website advertised it. That's not them using it. So,
14:12:27 how about you give me where you have a well-pleaded
14:12:32 complaint that says something more than we think they used
14:12:35 it.
14:12:35 MR. BRAMHALL: Well, so Your Honor, there is --

14:12:37 the website address that you're talking about was a website
14:12:42 for this commercial product. It had a requisition form for
14:12:46 ordering the product --
14:12:47 THE COURT: Not infringement.
14:12:48 MR. BRAMHALL: For use, Your Honor.
14:12:49 THE COURT: But it's an advertisement. I can
14:12:51 advertise all kinds of stuff. It doesn't mean anyone is
14:12:54 actually using it. Maybe if they do actually sell it, it
14:12:58 would be an act of inducing infringement. I'm asking where
14:13:01 you have alleged that they used it?
14:13:04 MR. BRAMHALL: So two other paragraphs, Your
14:13:06 Honor. 67, and apologies for going backwards. That's a
14:13:12 paragraph that talks about the development of the test, the
14:13:14 accused test --
14:13:15 THE COURT: Where do you say how that is not
14:13:18 covered by the Safe Harbor?
14:13:20 MR. BRAMHALL: So, Your Honor, we have
14:13:21 allegations in our complaint that make it very clear we're
14:13:23 not capturing --
14:13:24 THE COURT: I'm asking you to give me your
14:13:27 allegations, give me a paragraph. You're citing paragraphs
14:13:29 where you talk about advertising and you're giving me
14:13:33 paragraphs where you talk about development. What is it
14:13:35 that you say is a well-pleaded paragraph that they used it
14:13:40 in a way that is not covered by the Safe Harbor?

14:13:44 **MR. BRAMHALL: So, Your Honor, the rest of that**
14:13:46 **paragraph, 67, and I would argue that overall our**
14:13:49 **allegations are --**
14:13:50 **THE COURT: Well, I'm not doing a gestalt over**
14:13:55 **gestalt thing, I want to see your well-pleaded paragraphs**
14:13:57 **and if you can't point me to them, then perhaps they're not**
14:14:00 **so well pleaded, because I'm not reading a hundred**
14:14:04 **paragraphs and saying well, I kind of see it, feel it, okay.**
14:14:08 **MR. BRAMHALL: Your Honor, admittedly there is**
14:14:11 **not a ton of information --**
14:14:13 **THE COURT: Well, maybe admittedly you shouldn't**
14:14:16 **be arguing infringement and you should stick with your**
14:14:18 **declaratory judgment counts because you don't have a good**
14:14:21 **faith basis to assert that they have used it.**
14:14:24 **MR. BRAMHALL: And, Your Honor, that's exactly**
14:14:26 **what we've done in our new complaint --**
14:14:28 **THE COURT: Okay.**
14:14:28 **MR. BRAMHALL: In the new complaint --**
14:14:30 **THE COURT: Well, that's not what I have in**
14:14:31 **front of me and you haven't moved to amend or to supplement**
14:14:35 **or to do anything else and I'm dealing with the complaint**
14:14:38 **that's in front of me. So maybe you fixed it going forward**
14:14:41 **but you didn't fix it here.**
14:14:43 **So Count One, the best you have is paragraph 69,**
14:14:48 **67 and what?**

14:14:50 **MR. BRAMHALL: 85 is another paragraph. It says**
14:14:52 **Geneoscopy has its own CLIA certified laboratory -- that's a**
14:14:56 **laboratory that runs these LDT tests -- in the United States**
14:14:59 **that has performed, or will perform Exact Sciences' patented**
14:15:04 **methods using one or more of the accused products. Again,**
14:15:07 **encompassing the LDT tests.**
14:15:12 **THE COURT: All right.**
14:15:13 **MR. BRAMHALL: Your Honor, we're at the pleading**
14:15:15 **stage --**
14:15:16 **THE COURT: Are you planning to amend or**
14:15:17 **supplement this pleading now that they have received FDA**
14:15:21 **approval?**
14:15:21 **MR. BRAMHALL: Your Honor, our intent actually**
14:15:23 **is to bring both of the complaints together through**
14:15:25 **consolidation and we actually asked counsel --**
14:15:28 **THE COURT: That's not answering my question,**
14:15:29 **I'm asking are you planning to amend or supplement this**
14:15:33 **complaint. Because consolidation doesn't do anything with**
14:15:36 **respect to that answer. Right?**
14:15:39 **MR. BRAMHALL: Sure. So Your Honor, yes,**
14:15:40 **absolutely. We intend to bring this complaint up-to-date**
14:15:43 **with the allegations in the other --**
14:15:45 **THE COURT: So why didn't you say you were going**
14:15:47 **to do that so that I have to decide a motion to dismiss?**
14:15:53 **Because clearly if you did that, or asked for permission to**

14:15:56 do that, it might moot the particular issues in this motion
14:16:00 to dismiss. Right?
14:16:01 MR. BRAMHALL: Your Honor, I'm happy to make
14:16:03 that request now.
14:16:04 THE COURT: No, I think you really should have
14:16:05 made it before you came in.
14:16:07 All right. Okay. I think I understand Count
14:16:11 One.
14:16:11 All right. Count Two. Let me ask the
14:16:15 defendants, how is there not enough here to meet these
14:16:22 standards for declaratory judgment jurisdiction?
14:16:28 MS. BURG: Thank you, Your Honor.
14:16:31 With respect to declaratory judgment
14:16:33 jurisdiction, Your Honor, fundamentally Exact filed this
14:16:39 complaint, they jumped the gun and filed too early. All of
14:16:43 the accused activities which are generally contained in the
14:16:46 purported claim chart are part of Geneoscopy's clinical
14:16:51 trials that it conducted in support of its efforts to seek
14:16:55 FDA approval, so all of those activities are protected by
14:16:59 the Safe Harbor.
14:17:00 THE COURT: But they don't have to argue that
14:17:02 they actually infringed, they're saying you are -- that
14:17:07 there is anticipation that you are going to and presumably
14:17:11 you're not getting FDA approval so that you can sit on it
14:17:15 and nobody could ever use the methods; right?

14:17:18 **MS. BURG: Well, respectfully, Your Honor, as --**

14:17:23 **THE COURT: There is a substantial controversy between the parties of sufficient immediacy and reality, so you're asking for FDA approval to sell this thing. You now have FDA approval. I know you say well, that doesn't matter because they -- they filed the complaint beforehand, but why isn't that enough?**

14:17:54 **MS. BURG: Your Honor, so there is a couple of things. As you stated, first Exact jumped the gun and didn't have jurisdiction at the time of the filing of the complaint when FDA approval was uncertain. Since they filed in November, they have been saying for months that FDA approval was imminent, but the reality is that Geneoscopy is an innovator bringing a new technology to market, got a breakthrough designation by FDA and ultimately did receive that approval just on May 3rd, but that approval was not certain from Geneoscopy's perspective and FDA approval is never uncertain and the purpose of the Safe Harbor is to insulate innovator Geneoscopy and drug makers as well from potential liability from patent infringement.**

14:18:41 **THE COURT: There is no liability from that stuff that would be included under the Safe Harbor, it doesn't mean that they -- that doesn't necessarily mean that they can't sue you for declaratory judgment based on an immediate and real controversy or, you know, a fear that**

14:19:09 you're going to do something, right?

14:19:12 MS. BURG: Well, Your Honor, we're not

14:19:14 contesting the concept that that could --

14:19:16 THE COURT: If they were saying only that oh,

14:19:18 everything you did in order to get approval was what they

14:19:21 were basing it on, that's fine, but they're not. They're

14:19:24 saying you're going to go out and tell people you're already

14:19:28 putting things on the website where order forms on the

14:19:32 website, I don't know if your client is or not, but they're

14:19:37 saying there are already ways that you could offer it for

14:19:40 sale that presumably then people would use it.

14:19:43 MS. BURG: Well, Your Honor, a couple of points.

14:19:46 So first, I want to come back to the fact that the '781

14:19:50 patent only asserts method claims, that all steps must be

14:19:53 performed for the method to be infringed. And what

14:19:57 Geneoscopy ultimately hopes to bring to market, it has not

14:20:00 launched yet and may not launch for quite some time, and

14:20:03 certainly there is no certainty as to approval as of the

14:20:07 time the complaint was filed in November of 2023, but

14:20:11 Geneoscopy at most may create a kit which Exact contends

14:20:16 when used may cause a patient to directly infringe by

14:20:22 performing all of the claimed steps of the method.

14:20:24 And so this is different, I think, even less

14:20:28 immediate than the cases from this district in *Juno* and

14:20:32 *Clarus* in which the district granted a motion to dismiss for

14:20:36 lack of immediacy where the FDA approval was pending and
14:20:41 prior to launch, and I think in the *Clarus* case, Judge
14:20:45 Andrews stated that it was to get to the point of immediacy
14:20:47 it had to be both approved and ultimately come to market and
14:20:51 those events haven't come to pass.
14:20:54 And here because of the nature of the claims, I
14:20:56 think it's even more removed and less immediate. And
14:21:00 fundamentally this is a case where Exact has jumped the gun
14:21:04 too early by filing so early in the process when approval
14:21:08 was pending --
14:21:09 THE COURT: You didn't move to dismiss the
14:21:10 lawsuit that was just filed on the same grounds?
14:21:15 MS. BURG: Your Honor, we have not fully
14:21:17 reviewed that complaint yet, so I'm not certain of all the
14:21:21 allegations yet, so I don't have a position on that today.
14:21:26 THE COURT: Do you think that if they were to
14:21:29 have filed it today, the complaint that they filed in this
14:21:36 case now that FDA approval has been granted, that they would
14:21:44 have declaratory judgment jurisdiction?
14:21:47 MS. BURG: Your Honor, I still think that today
14:21:50 it's a stretch to say there is declaratory judgment
14:21:52 jurisdiction because of the amount of time it would take to
14:21:55 commercially launch.
14:21:56 THE COURT: So there is a time requirement on
14:21:58 the declaratory judgment, it can't be that as soon as you

find out about the reimbursement, whether that's in a day or in a year, you say well, gosh, because it could be nine to twelve months, then it's not sufficiently immediate?

MS. BURG: Yes, Your Honor. I think there is some case-by-case and some fact specific situations. As this case shows here, the *Amarin* case that we have on the slide that FDA approval does not create declaratory judgment jurisdiction prior to launch. There what Judge Sleet concluded where a complaint seeking a declaratory judgment of patent infringement had been filed after FDA approval but prior to product launch, and the patents at issue asserted method claims, what Judge Sleet found was that these were methods that would have to be conducted in the -- the results would be in patients and those physiological reactions had not even occurred yet, so if a product launch date remained uncertain, the potential future infringement was not sufficiently immediate to support the exercise of declaratory judgment jurisdiction.

THE COURT: Okay.

MS. BURG: Thank you, Your Honor.

MR. BRAMHALL: Thank you, Your Honor. May I respond?

THE COURT: You may.

MR. BRAMHALL: And Your Honor, all Exact Sciences has done here is taken Geneoscopy at its word going

back to the original complaint. This is some of the evidence that we cite back from November of 2023 where Geneoscopy has talked to the St. Louis Business Journal about the fact that it's going to soon begin commercializing its tests.

If we could go to the next slide.

And Geneoscopy actually repeated this statement in a press release around the very same time, announcing this massive deal, this Labcorp deal, where Labcorp stands ready today to distribute its entire sales force to distribute the product as soon as it gets the go ahead from Geneoscopy. This was true back in November of 2023. There is no question in our minds that there was jurisdiction at the time, we were relying on what they were telling the market and they were telling us.

With regard to these cases counsel cited, with respect to *Amarin,* in that case it was uncertain whether the product would ever be released. It wasn't a question of whether there was approval or not, it was a question of whether the product would ever be released. That's not the situation here. It's just a matter of time, Your Honor, it is certain that the product will be released.

With respect to *Juno* and *Clarus*, these two cases, those cases have much more uncertain allegations as well. Our situation is much more like the *Allergan* case in

14:24:43 the sense that that's a Judge Hall and Judge Andrews' case,
14:24:47 where there was stockpiling. And I would argue that this
14:24:47 Labcorp deal is essentially the equivalent of stockpiling,
14:24:54 it's getting ready to infringe in a very significant way,
14:24:55 and so I think just without belaboring the point, Your
14:24:58 Honor, there is much more amnesty.
14:25:00 And one thing I want to point out with respect
14:25:02 to what Geneoscopy has been saying since our initial
14:25:05 complaint about approval and commercialization, if can we
14:25:09 get up slide number 11, please. This is an interview in
14:25:13 January of this year where Erica Barnell, the CSO of
14:25:19 Geneoscopy, Dr. Erica Barnell, "I think we'll be able to be
14:25:23 in the hands of patients very shortly after FDA approval."
14:25:25 Your Honor, in April, as Geneoscopy was
14:25:29 realizing is was going to have approval, this is slide 16,
14:25:32 I'll tell you that last slide and this one in our new
14:25:37 complaint, not our old one because we weren't aware of this
14:25:40 evidence, this is Mr. Andrew Barnell, who is the CEO of the
14:25:45 company, was telling investors. He was showing FDA approval
14:25:48 in 2024, followed by an immediate ColoSense product launch.
14:25:53 That's not what we heard today, but that's what they told
14:25:57 investors, and that's, Your Honor, the world we are living
14:26:00 in in terms of immediacy and jurisdiction.
14:26:03 THE COURT: Okay. For the defendants, give me
14:26:06 what your thinking is on the Lanham Act claim. It seemed

like a lot of your motion was based on the fact that there was not approval -- actually, before we get to the Lanham Act, tell me about stockpiling. Is the company making these things, stockpiling them for sale as soon as they hopefully get reimbursement?

MR. WARE: Your Honor, I don't actually know the answer to that question, but I think it's very important to remember that this is not a patent that has anything to do with a product. And stockpiling a product cannot infringe this patent.

THE COURT: No, no, I get it. I'm the one who keeps saying it's not making or selling or offering to sell, I get that. I'm not an idiot. But that doesn't mean that when you're -- if your client were stockpiling the stuff in order to sell for people to use and they would say using is infringing, that goes into me looking at whether or not there is declaratory judgment jurisdiction.

So that's why I asked. Okay. Lanham Act.

MR. WARE: Okay. So on the Lanham Act, I think I would like to say something first if I may, Your Honor, on primary jurisdiction. And the complaint, when we received this amended complaint with thirty0 pages of highly technical criticisms of Geneoscopy's clinical trial data from its phase three trial such as the size of patient cohorts or enrollment protocols, statistical significance of

14:27:57 data outcomes, my first reaction was are they really asking
14:28:02 the Court to determine the safety and efficacy of ColoSense
14:28:06 rather than the FDA.
14:28:07 As we've seen in the briefing, the answer is
14:28:09 yeah, that's exactly what they're doing. And it is very
14:28:13 hard for me to imagine technical issues that would be more
14:28:17 uniquely within the special expertise of the FDA than that
14:28:21 thirty pages of allegations about patient cohorts or
14:28:25 everything else.
14:28:25 The FDA has hundreds of medical professionals,
14:28:30 biostatisticians, that's what their job is to do.
14:28:32 And then on top of that, we read in footnote 93
14:28:36 of the Amended Complaint that they filed that they had
14:28:38 already filed a trade complaint in the FDA against this
14:28:43 product trying to persuade the FDA not to approve it.
14:28:46 And this case, I would say --
14:28:50 THE COURT: What footnote did you tell them to
14:28:56 look at?
14:28:57 MR. WARE: In the Amended Complaint that it was
14:29:00 filed, whatever day that was, footnote 93 referred to a
14:29:04 trade complaint --
14:29:05 THE COURT: Hold on. Stop talking until I can
14:29:08 find it. I want to read it so that I understand what you're
14:29:12 telling me. I got it. It's on page 67. It's just a URL.
14:29:21 So what am I doing here?

14:29:24 **MR. WARE: So in our -- in the exhibits attached**
14:29:27 **to our motion to dismiss, Exhibit 3, and it would be**
14:29:39 **page 67, and the footnote cites FDA's --**
14:29:43 **THE COURT: I'm sorry. You told me to look at**
14:29:45 **footnote 93 of the Amended Complaint?**
14:29:49 **MR. WARE: Yes, so let me explain --**
14:29:51 **THE COURT: So footnote 93 of the Amended**
14:29:54 **Complaint is a URL to a Facebook post.**
14:29:57 **MR. WARE: I understand, Your Honor. Let me**
14:29:59 **explain why there is the confusion. The complaint that was**
14:30:02 **filed, the Amended Complaint that was filed is attached as**
14:30:04 **Exhibit 3 to Ms. Burg's declaration. After it got filed and**
14:30:08 **we brought it to their attention and we asked them for a**
14:30:12 **copy of the trade complaint, they said, oh, that was a**
14:30:15 **mistake, we didn't mean to cite that in footnote 93. So**
14:30:19 **they called up the clerk and said we want to replace that**
14:30:23 **complaint, Amended Complaint, with another complaint. Okay?**
14:30:26 **So what is on the Court's record now does not**
14:30:29 **have footnote 93 that was served on us, but the point is**
14:30:33 **what was served on us told us that there was a trade**
14:30:36 **complaint in the FDA regarding Geneoscopy's promotion of**
14:30:44 **colorectal cancer screening tests in violation of the Food,**
14:30:48 **Drug and Cosmetic Act.**
14:30:50 **So that fact is not present in a lot of the**
14:30:54 **primary jurisdiction cases. A case that we cite where**

14:31:01 something like that was true was the *Endo* case where the
14:31:05 court dismissed where the plaintiff had made application to
14:31:08 the FDA on the same issue that it was trying to put before
14:31:12 the court. The court dismissed that it would be improper
14:31:15 for the court to make a determination on an issue before the
14:31:18 FDA.

14:31:18 So as a matter of judicial efficiency, we don't
14:31:22 think it makes any sense to wade into the clinical data. It
14:31:26 also, citing the *Baykeeper* factors that we run the risk of
14:31:33 conflicting rulings on the same questions of fact.

14:31:36 So now, we don't know precisely what's in that
14:31:40 FDA complaint because Exact refused to provide it to us.
14:31:44 But we think it's fair to assume given the thirty pages of
14:31:48 technical detail elaborating on Geneoscopy's clinical data
14:31:53 that probably the FDA complaint says the same thing. And it
14:31:57 would have been easy for them to say oh, no, it's before the
14:32:00 FDA, we raised different issues. But they chose not to.
14:32:05 They chose just to say oh, it was a mistake. So we really
14:32:09 think that primary jurisdiction doctrine is perfectly
14:32:13 addressed to this problem.

14:32:15 And I think I also would like to emphasize a
14:32:19 policy point, and that is the proposition that's being
14:32:22 asserted here is that they can attack the reliability of the
14:32:27 same data that the FDA uses to determine the safety and
14:32:31 efficacy of this test. And if this were true, any company

14:32:38 would attack after the fact the FDA's determination of
14:32:41 safety and efficacy of a competitor's drug or device and try
14:32:47 to get a jury to disagree with the FDA after the fact.
14:32:50 We think this would be a very bad idea, that
14:32:55 courts would see a flood of Lanham Act cases that would
14:32:58 attack a competitor's FDA approval saying oh, it's false
14:33:02 advertising. The FDA, you may have said it's safe and
14:33:06 efficacious, but we're going to prove in court that it isn't
14:33:10 safe and efficacious, that would be a huge, huge expansion
14:33:14 of the Lanham Act.
14:33:15 THE COURT: Is it really that that they're
14:33:17 complaining about or is it that you are saying we are better
14:33:21 than, that they say that your client is saying you're
14:33:25 superior or you're better than when that's not it. That
14:33:27 seems to me to be different than just saying it's not a safe
14:33:31 and efficacious product, they're saying it's safe and it's
14:33:35 not.
14:33:35 MR. WARE: I would submit, Your Honor, that
14:33:37 they're saying both, they're absolutely saying both and
14:33:41 their FDA trade complaint also put the issue of promotion in
14:33:44 front of the FDA. They are saying both.
14:33:46 Now, as far as that goes, when we talk about the
14:33:50 elements of the Lanham Act claim, we do address that and
14:33:52 what they're complaining about is a statement about the
14:33:56 data, the sensitivity data that was in the Journal of

14:34:01 American Medical Association. And Geneoscopy said that was
14:34:04 the highest that had been reported of any such test.
14:34:09 The journal itself where that was drawn from
14:34:13 specifically said there was no head-to-head comparison. And
14:34:17 that's really what they're complaining about is false and
14:34:21 misleading. They're saying well, that Geneoscopy is
14:34:23 implying that there was a head-to-head comparison and yet
14:34:28 the very data, the very source of data that we refer to,
14:34:31 that we refer the reader to said there was no head-to-head
14:34:35 comparison, it's just that number is higher than the number
14:34:38 that came out of their clinical trial. That's it. But in
14:34:41 any case, they put that issue before the FDA as well.
14:34:43 THE COURT: All right. Let me hear from the
14:34:48 plaintiff on those issues first.
14:34:50 MR. WARE: Okay. Great. Thank you.
14:34:52 THE COURT: So this mysterious trade complaint
14:34:55 that you all referred at and then took back, but apparently
14:34:58 it exist. Right?
14:34:59 MR. BRAMHALL: It does exist, Your Honor.
14:35:01 THE COURT: Tell me what is being asserted here
14:35:04 that is not -- don't tell me what's in there, in the trade
14:35:08 complaint, tell me what is here that is not also asserted in
14:35:13 the trade complaint.
14:35:14 MR. BRAMHALL: So what is at issue here, Your
14:35:16 Honor, are Lanham Act claims that are about commercial

14:35:19 promotion --

14:35:20 THE COURT: No, no, no, tell me what the basis
14:35:22 is. I know, because I take his point, he's like look, if
14:35:26 you just are going to get to go in and say they lied, they
14:35:31 lied, and the FDA is the one who is determining whether it's
14:35:35 safe and efficacious, I don't want to really open up the
14:35:39 Lanham Act claim saying my product is safe and efficacious.
14:35:43 So I defer to the FDA on some of that. Don't tell me the
14:35:47 Lanham Act is different from what FDA does, tell me what
14:35:51 assertions you have, what complaints you have that are not
14:35:56 in the mysterious trade complaint that nobody seems to know
14:36:00 what's in but you all.

14:36:01 MR. BRAMHALL: So the mysterious trade complaint
14:36:04 Your Honor, is about safety and efficacy of the ColoSense
14:36:08 test and claims surrounding that --

14:36:11 THE COURT: What is not -- tell me what in the
14:36:14 current one is not in the trade complaint.

14:36:16 MR. BRAMHALL: So the complaints in this -- our
14:36:18 allegations in this complaint are much more robust. That's
14:36:21 a short letter, Your Honor, it's a handful of pages --

14:36:25 THE COURT: Just tell me, show me, give me some
14:36:29 assertions here.

14:36:32 MR. BRAMHALL: So, Your Honor, it's right to
14:36:34 focus on -- so the trade complaints, there is overlap, we're
14:36:38 not denying that, but that doesn't mean Your Honor should

14:36:42 abstain from jurisdiction --

14:36:44 THE COURT: Let's put it this way. I am not
14:36:46 dealing with stuff that is in front of the FDA. So if you
14:36:49 don't want me to dismiss your Lanham Act claims, you better
14:36:53 point me to something that you can represent to me is not
14:36:57 before the FDA on the trade complaint.

14:37:00 MR. BRAMHALL: So, Your Honor, I don't think the
14:37:02 --

14:37:02 THE COURT: Point me to some allegations.

14:37:05 MR. BRAMHALL: Your Honor, I don't think the
14:37:06 trade complaint is in front of the FDA at all because the
14:37:08 product has been approved, so the product has been approved,
14:37:11 that puts this whole thing to rest. But that doesn't
14:37:14 address, Your Honor, the past commercial marketing that they
14:37:17 were doing that was false and misleading including with the
14:37:21 superiority claims. We're entitled, Your Honor, to seek
14:37:23 remedy --

14:37:24 THE COURT: Are you going to argue that it's
14:37:26 false and misleading to say that their product is safe and
14:37:29 efficacious?

14:37:29 MR. BRAMHALL: No, we're not, Your Honor.
14:37:31 That's not at all what we're arguing. We're arguing about
14:37:34 the representations that they're making to the commercial
14:37:37 public about their test versus our test which are not
14:37:39 supported by -- these are classic, Your Honor, establishment

14:37:42 claims under *Southland Sod*, they are completely permissible
14:37:43 and there is no reason why Your Honor should advocate your
14:37:48 jurisdiction here. The *POM Wonderful v. Coca-cola* case
14:37:53 makes very clear that the FDA and the Lanham Act are
14:37:56 separate and complimentary.
14:37:58 THE COURT: It doesn't matter to me. If you
14:38:00 were saying we're going after -- I get it, they're two
14:38:04 separate statutes, but that doesn't mean that I'm going to
14:38:08 go out of my way to say I have jurisdiction over claims if
14:38:13 it's something like the safety and efficacy.
14:38:16 MR. BRAMHALL: It's absolutely not.
14:38:19 THE COURT: That's why I'm asking you. Don't
14:38:21 just tell me, Your Honor, they're different statutes, so
14:38:24 you're stuck, you got to deal with it because we asserted
14:38:27 it, that's not where you're going to get me. Okay? I'm
14:38:30 asking you what's different and I'm assuming that you're
14:38:33 saying what's different is they made claims of superiority.
14:38:39 MR. BRAMHALL: Yes, that's correct. In
14:38:43 commercial promotions to physicians and others in a way that
14:38:48 is deceiving to them and we've been harmed as a result, both
14:38:54 in the past and prospectively we have been harmed by these
14:38:57 claims, which they continue to make. They literally are
14:39:01 making these claims today at a conference called DDW,
14:39:06 Digestive -- I'm not going to be able to get the acronym,
14:39:09 but it's a conference literally today where we saw reporting

14:39:12 from yesterday where they're making the same misleading
14:39:15 claims where they're claiming a hundred percent sensitivity
14:39:19 and not saying, Your Honor, they are omitting the key
14:39:19 information that there are only five cancers that that's
14:39:22 based on, there is an N equals five, and statistically
14:39:25 that's a very misleading and false claim to make because it
14:39:29 suggest to a user, a physician, that this test is perfect
14:39:32 and they must have had a statistically powered study when
14:39:37 they didn't. That's the nature of our Lanham Act claims,
14:39:39 Your Honor.

14:39:40 THE COURT: Okay. And you're saying the FDA at
14:39:44 this point is out of it, so even if we were to assume that
14:39:48 the FDA had primary jurisdiction, there is nothing for the
14:39:51 FDA to decide right now.

14:39:52 MR. BRAMHALL: They're going to deal with the
14:39:54 label, Your Honor, and the safety and efficacy. We're
14:39:57 dealing with the commercial promotion and the harm to us.
14:39:59 That's what we're doing, which is exactly what the Lanham
14:40:02 Act is for.

14:40:02 THE COURT: All right. Let me hear from
14:40:05 Mr. Ware on that point.

14:40:10 MR. WARE: So first of all, on that point, what
14:40:13 you just heard was actually that through the Lanham Act they
14:40:17 want to challenge the safety and efficacy --

14:40:20 THE COURT: No, what I heard was they're

14:40:23 complaining that there are statements made that are not
14:40:26 supported as to whether -- I'm not saying whether this is
14:40:32 true or not, this is the allegations. There are statements
14:40:36 being made, including as of yesterday, that this product is
14:40:39 superior to their product.
14:40:41 MR. WARE: All right. So let me address that.
14:40:43 So the issue -- that issue we believe, and they certainly
14:40:47 didn't deny that that issue is also before the FDA. The
14:40:50 trade complaint that they filed was a trade complaint
14:40:54 against promotional activities of Geneoscopy. The FDA has
14:41:00 statutory jurisdiction to consider claims that promotional
14:41:05 activities including comparative advertising are unlawful,
14:41:10 and that's 21 CFR 202.1(e)(6).
14:41:15 THE COURT: Right. But I have had cases in the
14:41:17 past where there is an assertion from the FDA that there was
14:41:24 an improper comparison and you get a letter, I forget what
14:41:28 they're called, but you get a letter from the FDA saying you
14:41:31 can't make that superiority claim, that's not supported by
14:41:34 the clinical data. That doesn't preclude a Lanham Act claim
14:41:38 because in those cases where I have seen those most usually
14:41:42 there was a Lanham Act assertion.
14:41:44 MR. WARE: Well, I think what makes this case
14:41:46 different, perhaps, is that that issue is actually pending
14:41:49 before the FDA right now.
14:41:50 THE COURT: It's not pending before the FDA

14:41:53 because the FDA is not doing anything because you have
14:41:56 approval.
14:41:57 MR. WARE: Well, if I may, Your Honor, what he
14:42:00 said was the issue of safety and efficacy was not before the
14:42:03 FDA. He did not say the issue of comparative advertising is
14:42:07 not before them.
14:42:07 THE COURT: Right. Is the issue of comparative
14:42:11 advertising in the trade letter?
14:42:13 MR. BRAMHALL: Comparative advertising?
14:42:15 THE COURT: The stuff that you just told me, the
14:42:17 comparative advertising where they're saying their product
14:42:20 is better than yours, is that in the trade letter?
14:42:22 MR. BRAMHALL: Yeah, in the context of safety
14:42:25 and efficacy, that's what we're dealing with, that was about
14:42:28 approval. That's what we are addressing. Your Honor, this
14:42:31 was back in November. This hasn't gone anywhere. We're
14:42:35 coming to Your Honor to have our harms addressed including
14:42:38 again for pre-approval advertising, that was widespread and
14:42:42 that again, continues to this day.
14:42:44 MR. WARE: Well, in other words, it is before
14:42:46 the FDA, they haven't acted on it. It's exactly the same
14:42:50 issue that they would like to put before this judge.
14:42:52 THE COURT: But I'm sorry, isn't the trade
14:42:55 letter -- is he correct that the trade letter was seeking to
14:42:59 keep approval from happening? And so if that's the case,

14:43:03 now that approval has been granted, isn't it -- it doesn't
14:43:10 sound like there is anyone active on that letter.
14:43:13 MR. WARE: First of all, we haven't seen it, so
14:43:15 I can't really speak to that. But what it was addressing,
14:43:17 it was addressing two things. It was addressing safety and
14:43:20 efficacy which they sought to persuade the FDA wasn't there,
14:43:24 and it was addressing the promotional activities, the
14:43:28 pre-approval promotional activities that you have just been
14:43:31 hearing about, it says so explicitly in the title.
14:43:34 THE COURT: And presumably they're going to
14:43:37 amend and supplement their complaint, not just pre-approval
14:43:41 activities that they're complaining about, apparently you
14:43:43 all keep saying it and that's not pre-approval. Anything,
14:43:47 assuming that what was represented to me happened yesterday,
14:43:51 that's not pre-approval, right?
14:43:53 MR. WARE: I know absolutely nothing about that.
14:43:56 I know in the press release they put out, they made no such
14:44:01 statement, so I don't believe it's actually true. But
14:44:04 whether it's pre-promotional or simply promotional activity,
14:44:07 the FDA has jurisdiction over the issues pending before
14:44:08 them. I would suggest that Exact provide us and the Court a
14:44:12 copy of the letter and we could address this in a more
14:44:15 sensible way.
14:44:17 THE COURT: Why didn't you give them a copy of
14:44:19 it? Why did you just say we're taking out that footnote and

14:44:24 switching out the footnote so I didn't see it? How come you
14:44:27 didn't give me that?
14:44:28 MR. BRAMHALL: Your Honor, it was not intended
14:44:31 to be part of the complaint. It was included in error.
14:44:33 It's not part of our allegations.
14:44:35 THE COURT: I know it's not part of your
14:44:38 allegations, it's part of why they say I shouldn't exercise
14:44:41 jurisdiction over the Lanham Act claim, and now you didn't
14:44:43 even give them a copy. And he's just saying, I don't even
14:44:47 know what to tell you, judge. Everything before you could
14:44:50 be in front of the FDA. They won't even give me a copy of
14:44:53 it. You don't even know that it's just a short letter, do
14:44:56 you, Mr. Ware?
14:44:57 MR. WARE: I don't. I don't. It might be
14:45:00 thirty pages long.
14:45:01 THE COURT: It shouldn't be that hard. How come
14:45:03 you didn't give it to him?
14:45:06 MR. BRAMHALL: We didn't think it was relevant,
14:45:08 Your Honor, even if she had raised the exact same issues --
14:45:12 THE COURT: I get it, you're saying you still
14:45:14 have an argument and I'm saying it's a less persuasive
14:45:18 argument to me. I keep asking you, what's in the complaint
14:45:21 that's not in the letter? And I'm not sure that I actually
14:45:24 know except that you told me that there are post approval
14:45:27 statements that you want to assert, but those are not in the

14:45:31 1 **First Amended Complaint because the First Amended Complaint**
14:45:33 2 **was filed prior to approval.**
14:45:34 3 **MR. BRAMHALL: Exactly, Your Honor. And the**
14:45:36 4 **issue is, that was in November. There have been a whole**
14:45:39 5 **slew of additional ads that have been raised. We have not**
14:45:42 6 **gone back to the FDA as far as I am aware. We're here with**
14:45:48 7 **Your Honor as far as the Lanham Act, that's where we think**
14:45:48 8 **it should be adjudicated from the commercial harm**
14:45:50 9 **standpoint. Again, we're not challenging the efficacy and**
14:45:52 10 **safety, that's not what we're doing with this claim.**
14:45:55 11 **MR. WARE: I don't think any of the statements**
14:45:56 12 **about the so-called advertising, I don't think they're true**
14:45:59 13 **to begin with, but nevertheless they're certainly not before**
14:46:02 14 **the Court, they're not in any pleading. We are here on a**
14:46:05 15 **12(b)(6) motion to dismiss this pleading. They're also not**
14:46:10 16 **in the new complaint that was just filed.**
14:46:12 17 **MR. BRAMHALL: Your Honor, there is not a single**
14:46:14 18 **case cited by our opposition that says simply sending a**
14:46:18 19 **letter to the FDA deprives you of jurisdiction. I don't**
14:46:21 20 **think there is a case, and we have --**
14:46:23 21 **THE COURT: No, but when their argument is that**
14:46:27 22 **the FDA does have jurisdiction, and he does get some**
14:46:30 23 **resonance with me saying really, we're going to have**
14:46:32 24 **parallel proceedings, maybe you're not arguing safety and**
14:46:36 25 **efficacy, but do I want to open up, open up the gates for**

14:46:40 people to make those arguments and start making Lanham Act
14:46:43 claims out of really what shouldn't be Lanham Act claims but
14:46:46 should be issues for the FDA to determine?
14:46:53 MR. BRAMHALL: I think with all due respect,
14:46:54 Your Honor, I think these are strictly --
14:46:57 THE COURT: Whenever someone says "with all due
14:46:59 respect," I don't really take it as meaning that you're
14:47:02 saying that, so don't start that way. Okay?
14:47:05 MR. BRAMHALL: Your Honor, the way I see it is
14:47:07 Your Honor is particularly well situated to address these
14:47:10 kind of issues that are commercial in nature, not about the
14:47:14 safety and efficacy, these are strictly -- the Lanham Act
14:47:16 claims go to Your Honor for a reason. Your Honor, if they
14:47:19 would stop making these claims, perhaps we would rethink
14:47:23 this Lanham Act claim, but the reality is they're not so we
14:47:26 have to do something about it. So we're availing our rights
14:47:29 under the Lanham Act.
14:47:31 MR. WARE: Let me talk for a moment --
14:47:32 THE COURT: Let's stick with what's in the
14:47:34 complaint because that's really what I have to base this on.
14:47:37 If you're telling me, Your Honor, I can supplement, Your
14:47:40 Honor, I can amend, okay, but that's not helping me with
14:47:43 what's in your complaint that is in front of me.
14:47:49 MR. BRAMHALL: And, Your Honor, I'm happy to
14:47:50 explain. So if we back up for a moment, we have a series of

14:47:54 1 **different false advertising claims. There are a number of**
14:47:56 2 **them that are establishment claims that are under *Southland***
14:48:00 3 ***Sod* and there are two bases for that. One is premised on**
14:48:02 4 **the unreliability of the study. That's one bucket. The**
14:48:05 5 **second bucket is assuming the study is reliable, the claims**
14:48:08 6 **that they're making are not supported by any study. So**
14:48:11 7 **that's a totally different issue than even evaluating the**
14:48:15 8 **study from a reliability perspective, those are absolutely**
14:48:18 9 **in the case.**
14:48:18 10 **THE COURT: What I'm not sure about, when you**
14:48:20 11 **say reliability and sensitivity, are those really claims of**
14:48:24 12 **-- I understand when it's a comparison, but if they say our**
14:48:28 13 **product is, you know, this sensitive, are you really there**
14:48:31 14 **saying it's just not even sensitive enough that it works?**
14:48:35 15 **MR. BRAMHALL: So I think, Your Honor, they're**
14:48:37 16 **making clinical claims about sensitivity, for example,**
14:48:40 17 **saying it's a hundred percent, saying it has no false**
14:48:42 18 **negatives whatsoever, but then it's based on an N of five.**
14:48:46 19 **I think that's inherently false and misleading, because the**
14:48:50 20 **reader needs to know that this is not a clinical performance**
14:48:54 21 **claim that they can rely on. It's just not statistically**
14:48:59 22 **backed, Your Honor.**
14:49:00 23 **MR. WARE: Your Honor, if I may as to that**
14:49:02 24 **specific point just to put it in some context, what he's**
14:49:06 25 **talking about is an age cohort between age 45 and 49 and**

14:49:10 that's part of what they're seeking approval on. And Exact
14:49:14 wants to argue that the size of their cohort wasn't enough
14:49:18 to make that -- to make that data reliable. That's exactly
14:49:23 what the FDA considers when they decide whether the label
14:49:26 can cover people who are age 45 through 49. So the idea --
14:49:31 THE COURT: Let me ask you this. Then if the
14:49:35 label doesn't include that information and your client
14:49:41 continues to say it, does that mean that what, they're not
14:49:46 allowed to say that you're falsely advertising?
14:49:52 MR. WARE: I think the label sets up all the
14:49:54 data. The data says how many people are in every cohort.
14:49:58 THE COURT: Does the label let them say with
14:50:01 hundred percent among individuals age 45 to 49, sensitivity
14:50:07 was 100 percent among individuals? You're saying well, the
14:50:11 data is in there, somebody could see that.
14:50:15 MR. WARE: I think that my recollection is that
14:50:17 when you have a label, it also sets out in appendices what
14:50:21 all the data is that supports it. But for him to argue that
14:50:27 that's not challenging the safety and efficacy, if the FDA
14:50:31 is deciding --
14:50:32 THE COURT: Yeah, but this is a motion to
14:50:34 dismiss. I mean, at some point -- I can't make these, you
14:50:41 know, very detailed determinations on a motion to dismiss.
14:50:45 He's saying, I'm not challenging the safety and efficacy.
14:50:50 If he came back and it was summary judgment, maybe I would

14:50:54 1 understand what the arguments were being made and then I
14:50:57 2 would know that he was wrong. This is a motion to dismiss.
14:50:59 3 MR. WARE: Right.
14:51:00 4 THE COURT: He's got stuff in there saying these
14:51:02 5 claims are false, not that the product doesn't work at all,
14:51:06 6 not that people are going to be injured or harmed if they
14:51:09 7 use it, but that these claims, which have been reported and
14:51:16 8 repeatedly made outside of the FDA, are false.
14:51:22 9 MR. WARE: No, because, I'm sorry, Your Honor,
14:51:24 10 but the FDA wouldn't approve, they wouldn't approve a label
14:51:28 11 for a particular age cohort unless they reached a conclusion
14:51:33 12 --
14:51:33 13 THE COURT: No, no, no, the FDA doesn't require
14:51:35 14 you to show that it's a hundred percent sensitive for a 45
14:51:38 15 to 49 in order to approve it for that cohort, right, it
14:51:42 16 could be 85 percent and the fact is it might still be useful
14:51:47 17 and helpful. Right?
14:51:49 18 MR. WARE: What they have to do is they have to
14:51:51 19 decide that you have sufficient support for age 45 to 49 --
14:51:55 20 THE COURT: Right. And you are saying, assuming
14:51:57 21 your client is saying this, your client isn't just saying we
14:52:01 22 work and got approval in the 45 to 49 range, your client is
14:52:07 23 saying in fact in this range we had 100 percent sensitivity,
14:52:14 24 nothing -- no -- not going to miss anything. And they're
14:52:18 25 saying, why can't we argue that that is false, especially

14:52:23 **when you're going to keep saying it. I'm just saying what**
14:52:29 **their assertion is.**
14:52:30 **MR. WARE: Well, I go back to where I started**
14:52:33 **that I assume this is what they're arguing in the trade**
14:52:35 **complaint as well because they're complaining about**
14:52:37 **promotional activities and I assume that's one of the things**
14:52:40 **they're complaining about, so it would be very helpful if we**
14:52:43 **saw the letter and we can look at that.**
14:52:45 **Now, I can turn to a different subject on Lanham**
14:52:47 **Act which might be another way to go on this which is simply**
14:52:51 **that we don't believe that Exact at the time that they filed**
14:52:56 **the complaint had Article III standing to bring a Lanham Act**
14:53:00 **case. Again, this goes back to the FDA approval and the**
14:53:04 **uncertainty of FDA approval, but there is no case that's**
14:53:06 **been cited that has said that a party can bring a Lanham Act**
14:53:13 **case complaining about proximate -- harm proximately caused**
14:53:20 **by commercial advertising in the case of a party who does**
14:53:23 **not have an approved device, does not have a product on the**
14:53:28 **market.**
14:53:28 **So there is a -- there is a threshold question**
14:53:35 **of was there Article III standing when they brought this**
14:53:38 **case. It's not a question of whether they might have**
14:53:42 **Article III standing now, but in November of 2023. We**
14:53:49 **submit they did not have Article III standing to bring a**
14:53:52 **Lanham Act claim, again, to jump the gun long before there**

14:53:56 1 **is a product on the market, before anybody knows there is --**
14:54:00 2 **whether a product will be approved, there probably won't be**
14:54:04 3 **a product until the end of 2024, 2025, if at the earliest,**
14:54:09 4 **and so in November of 2023, the courts would say no, there**
14:54:15 5 **is no -- there is no standing to bring a Lanham Act action**
14:54:19 6 **at that time.**
14:54:22 7 **Parties are supposed to wait and see whether**
14:54:24 8 **there is actually competition in a market, whether somebody**
14:54:27 9 **is actually advertising, whether somebody is actually**
14:54:31 10 **seeking to influence purchasers. All we had in this case is**
14:54:36 11 **Geneoscopy saying we've applied for FDA approval. We have a**
14:54:40 12 **product. Here is the Journal of American Medical**
14:54:43 13 **Association report of our clinical trial. We think the data**
14:54:46 14 **is very good.**
14:54:47 15 **So I submit that there is no Article III**
14:54:50 16 **standing at the time. And, you know, we have made -- set**
14:54:58 17 **out some of the other elements of a Lanham Act case**
14:55:01 18 **including materiality including actually advertising to a**
14:55:05 19 **target audience, actually causing deception to that**
14:55:11 20 **audience, there is no allegation that supports those kinds**
14:55:14 21 **of elements either.**
14:55:17 22 **I know we've taken a lot of time and we've**
14:55:19 23 **addressed these in the brief. I'm happy to answer any**
14:55:22 24 **questions about them, but I wasn't going to go through them**
14:55:25 25 **one by one.**

14:55:26 **THE COURT: All right. Thank you.**

14:55:27 **Let me hear from you on standing. And if you do**
14:55:32 **file an Amended Complaint, maybe your date would go back to**
14:55:35 **the date of the original complaint, but if you filed a**
14:55:38 **supplemental complaint, my understanding is any new**
14:55:42 **information would get the date that the supplemental**
14:55:45 **complaint was filed. Do I have that right?**

14:55:47 **MR. BRAMHALL: You know, Your Honor, we looked a**
14:55:49 **lot into both of these issues. I think it would be some**
14:55:52 **mixture of a supplemental and Amended Complaint denied**
14:55:56 **depending on the allegations that we bring. I believe that**
14:55:59 **is correct. It is a confusing area of law, I will admit.**

14:56:03 **On the standing issue, can we get slide 21, I'll**
14:56:07 **deal with this briefly, Your Honor. From our perspective,**
14:56:09 **the Lanham Act specifically contemplates prospective**
14:56:14 **damages, from our perspective there is no issues with**
14:56:16 **standing. One, this is a 12(b)(6) issue, not a 12(b)(1)**
14:56:20 **issue, so Your Honor can accept our allegations as well pled**
14:56:23 **and as true.**

14:56:24 **With respect to this particular issue, there**
14:56:26 **were advertisements going back, these kind of**
14:56:30 **advertisements, they started back in October. And I think**
14:56:32 **we have a couple of examples here on slide 23. For example,**
14:56:37 **slide 24, so before November of 2023, they were making these**
14:56:43 **kind of claims, these advertising claims about the high**

14:56:46 sensitivity that compared the superiority claims that we
14:56:51 have an issue with, all the way back then prior to our first
14:56:54 complaint, so I don't think there is a real question here,
14:57:00 Your Honor.
14:57:00 THE COURT: All right. Anything further from
14:57:01 the defendants? Do you want to say on anything that maybe I
14:57:09 cut you off and did not let you say?
14:57:11 MR. WARE: No, Your Honor has been very generous
14:57:13 with our time. We've gone way past your time and I think
14:57:17 Your Honor has the issue.
14:57:18 THE COURT: Thank you. Anything further from
14:57:19 the plaintiff?
14:57:20 MR. BRAMHALL: I don't think so, Your Honor.
14:57:21 THE COURT: All right. So I have before me
14:57:23 defendant's motion to dismiss each of the counts of the
14:57:27 complaint. With respect to Count One, which asserts direct
14:57:32 infringement, I will dismiss that. I will dismiss it
14:57:35 without prejudice, but I don't think that the complaint -- I
14:57:39 think it's sloppily drafted and is talking about offering to
14:57:43 sell and making sales when the product hasn't been sold.
14:57:47 Perhaps there have been offers to sell, but all of the
14:57:51 claims in this patent as being asserted are method claims,
14:57:56 and so I just don't see that there is sufficient pleading in
14:58:01 there to assert direct infringement.
14:58:03 I will deny the motion to dismiss with respect

14:58:06 to Count Two, which is declaratory judgment, assertions of
14:58:15 declaratory judgment infringement. And there I do think
14:58:25 that there are sufficient facts alleged to create an actual
14:58:29 case or controversy. I think the plaintiff has pleaded
14:58:34 sufficient facts showing a dispute concerning infringement
14:58:37 that is of sufficient immediacy and reality to warrant the
14:58:41 issuance of declaratory judgment.

14:58:43 Geneoscopy keeps stating apparently, and even
14:58:46 has before this complaint was filed that it's prepared to
14:58:51 immediately launch the product upon FDA approval. I
14:58:55 understand that counsel has represented that there is
14:58:59 another step involved, but I think that there is sufficient
14:59:03 immediacy that has been alleged, including that it signed a
14:59:08 multiyear agreement with Labcorp to distribute the test upon
14:59:14 FDA approval. So I am going to deny that.

14:59:18 With respect to the Lanham Act claims, on this
14:59:21 one, I am sort of torn, but I do think that I guess this
14:59:27 would be Counts Three through Five, really. I do think that
14:59:32 there is probably a sufficient amount of well-pleaded
14:59:40 allegations to get to a Lanham Act claim. Perhaps not the
14:59:46 strongest of Lanham Act claims, but I think that it meets
14:59:54 the standard at this point.

14:59:56 As to standing, I do think that standing has
14:59:59 probably been sufficient standing, Article III standing. I
15:00:05 think it's also kind of a sliding scale what is necessary at

15:00:08 a particular time. You need more as you get further along
15:00:12 in the case and I think that what they've done here is
15:00:15 sufficient for the motion to dismiss stage.
15:00:21 Okay. So that is my ruling, the motion is
15:00:31 granted in part, denied in part. Plaintiff apparently is
15:00:35 going to be filing an amended or a supplemental or part or
15:00:42 both, pleading in the near future, and there is a question
15:00:48 about consolidation. Does defendant have a position on
15:00:51 whether these cases should be consolidated?
15:00:55 MR. WARE: Your Honor, I believe that the case
15:00:59 was just filed on Friday. I was traveling. We haven't even
15:01:03 discussed it with the client. I haven't even read it
15:01:05 actually to know what's in it.
15:01:07 THE COURT: I tried to pull it up, but I
15:01:09 couldn't get access today.
15:01:10 MR. WARE: May I ask one thing, Your Honor, just
15:01:13 in connection with the Lanham Act, since I do think the
15:01:15 issue of primary jurisdiction is important, could we request
15:01:19 that the plaintiffs provide us a copy of the trade
15:01:23 complaint.
15:01:23 THE COURT: Yes. Provide them with the trade
15:01:26 complaint.
15:01:27 MR. WARE: Thank you, Your Honor.
15:01:30 THE COURT: All right. Anything else that we
15:01:34 need to discuss while we're here?

15:01:37 **MR. BRAMHALL: I don't think so, Your Honor.**

15:02:16 **MS. BURG: Nothing further from defense, Your**
15:02:19 **Honor.**

15:02:19 **THE COURT: All right. Thank you, everyone.**
15:02:20 **Have a good rest of the week.**

15:02:23 **COURT CLERK: All rise. Court is adjourned.**

15:02:32 **(Court adjourned at 3:02 p.m.)**

I hereby certify the foregoing is a true and accurate transcript from my stenographic notes in the proceeding.

/s/ Dale C. Hawkins
Official Court Reporter
U.S. District Court